

**REMARKS**

This is a full and timely Response to the outstanding Office Action mailed June 2, 2004.

**1. Information Disclosure Statement**

Applicant acknowledges that page 2 of the Information Disclosure Statement submitted on February 9, 2004, was included with the Office Action mailed on June 2, 2004; however, page 1 of the Information Disclosure Statement was not included. Applicant respectfully requests that page 1 of the Information Disclosure Statement filed on February 9, 2004, be made of record and the references cited therein be considered by the Examiner.

Moreover, Applicant respectfully requests that the Information Disclosure Statements filed on August 4 and August 12, 2004, also be made of record and the references cited therein be considered by the Examiner. Copies of these Information Disclosure Statements and the cited references are enclosed.

**2. Amendment to the Claims**

Claims 1, 3, 4, 6-14 are amended to direct the claims to a wound dressing having at least one layer of conformable, conductive fabric having a surface resistance of less than 1,000 Ohms/cm<sup>2</sup>. The claim is further amended so that the fabric comprises a "uniformly" coated biologically inert polymer, and so that the wound dressing passively lowers the pathology's electrical potential by an amount effective to promote healing. Basis for these amendments are found throughout the specification as originally filed.

Claims 8-13 are amended to depend from claim 1.

Claim 15 is amended to correct a typographical error.

Claim 19 is amended to conform with the wound dressing of claim 1.

Claim 23 is amended to comprise a conformable, conductive wound dressing having a surface resistance of about 1 Ohm/cm<sup>2</sup>. The claim is further amended to recited that the wound dressing interiorly shifts a pathology's maximum electrical potential by an amount sufficient to induce an analgesic effect when in contact with the pathology. Basis for these amendments are found in the specification as originally filed, for example Table I.

Claim 28 is amended to recite that the polymer is coated using a solution electroless plating process.

Claim 31 is amended to recite a conformable, conductive fabric having a surface

resistivity of less than about 1 Ohm/cm<sup>2</sup>. Basis for this amendment is found in the specification as originally filed, for example Table I.

Claim 32, is amended to recite conformable, conductive fabric having a surface resistivity of less than about 1 Ohm/cm<sup>2</sup> and which interiorly shifts a pathology's maximum electrical resistance by an amount effective to promote healing and induce an analgesic effect. Basis for these amendments are found in the specification as originally filed, for example Table I.

Applicant submits that these amendments do not add any new matter.

### **3. Objection to Claim 15**

The Office Action objected to claim 15 because claim 15 contained a typographical error. Applicant amended claim 15 to change the spelling of "from" to --form--. Therefore, the objection to claim 15 is overcome.

### **4. Rejection of Claims 1, 4, 13 and 14 under 35 USC § 102**

Claims 1, 4, 13 and 14 are rejected under 35 USC § 102(b) as allegedly being anticipated by U.S. Patent No. 5,520,664 ("the '664 patent"). The '664 patent is cited as disclosing polymeric implants coated with antimicrobial metals such as silver. The Office Action concludes that although the '664 patent fails to explicitly teach a device configured to lower a pathology's electrical potential, the '664 patent inherently discloses this feature because the device disclosed in the '664 patent is allegedly made with the same conductive material as the claimed subject matter. Applicant respectfully traverses this rejection.

Applicant amended claim 1 to be generally directed to a wound dressing comprising, among other things, a conformable, conductive fabric. The '664 patent fails to disclose at least this element of claim 1, and therefore, the '664 patent fails to anticipate claim 1. Because claims 4, 13, and 14, ultimately depend from claim 1 and incorporate the limitations of claim 1, the '664 patent fails to anticipate claims 4, 13, and 14 for at least the reasons it fails to anticipate claim 1.

The Office action also notes that the '664 patent fails to disclose a conductive material having a resistance of less than 1000 ohms/cm. The Office Action points to pages 32-33 of Applicant's disclosure to show that the same metals have the same resistance. Applicant points out that claim 1 is amended to recite conductive materials having surface resistance less than about 1000 ohms/cm<sup>2</sup>. Pages 32-33 of the present disclosure provide the volume resistivity of metals. Surface resistivity and volume resistivity are different parameters.

Applicant draws the Examiner's attention to Table I on pages 43-44 of the present disclosure. Table I compares the surface resistivity of several different articles each containing various amount of silver in various configurations. The data show that articles containing silver can have significantly different surface resistivities. For example, one layer of a tricot Jersey knit autocatalytically plated silver nylon fabric has a measured surface conductivity of  $0.68 \text{ W/in}^2$  or  $\text{Ohms/in}^2$  (warp direction). In comparison, vapor deposited silver on Acticoat has a measured surface resistivity of  $1.70 \text{ W/in}^2$ . Thus, surface resistivity is not an inherent characteristic of a material.

Applicant also encloses the declaration of David E. Marx, Professor of Chemistry at University of Scranton, which describes the difference between surface resistivity and volume resistivity. Surface resistivity is defined as the ratio of the voltage to the current along its surface per unit of width of the surface. As a result, surface resistivity is numerically equal to the surface resistance between two electrodes forming opposite sides of a square. The size of the square is immaterial. Volume resistance is defined as resistance of a conductor of unit length, Ohm-cm. Surface resistivity is not an inherent property of a material (Declaration, paragraph 4). Because surface resistivity is not an inherent property of a material, the '664 patent fails to disclose, expressly or inherently, a conductive fabric having a surface resistance of less than 1000 ohms/cm<sup>2</sup> and cannot anticipate claims 1, 4, 13, and 14.

**5. Rejection of Claims 1, 4, 19, 23, 25-32 under 35 USC § 102**

Claims 1, 4, 19, 23, 25-32 are rejected under 35 USC § 102(e) as allegedly being anticipated by U.S. Patent No. 6,004,667 ("the '667 patent"). Applicant respectfully traverses this rejection.

First, the Office Action alleges that the wound dressing disclosed by the '667 patent inherently has a resistance of less than 1000 ohm/cm. Applicant respectfully disagrees and directs the Examiner's attention to the enclosed Declaration of Professor Marx. The Declaration of Professor Marx establishes that surface resistivity is not an inherent property of a material, and that the '667 patent fails to disclose the claimed subject matter because the device of the '667 patent does not have the claimed surface resistivity. Dr. Marx supports his analysis by noting that the device of the '667 patent has inconsistent application of a surface coating to the wound dressing. The changes in topography increase the surface resistance of the wound dressing

disclosed by the '667 patent. Thus, Dr. Marx states in his declaration that nothing in the '667 patent shows that wound dressing of the '667 patent has a surface resistance of less than 1000 ohms/cm<sup>2</sup>, and even if it does, it is doubtful that a resistance of less than 1000 Ohms/cm<sup>2</sup> could be maintained in actual use. Independent claims 1, 19, 23, and 32 each recite, among other things, a conductive fabric having a surface resistance of less than 1000 ohms/cm<sup>2</sup>. Claim 31 recites a surface resistance of less than 1 Ohms/cm<sup>2</sup>. The '667 patent fails to disclose a conformable, conductive fabric having a surface resistivity as claimed. Accordingly, the '667 patent cannot anticipate claims 1, 19, 23, 31, 32, and their dependent claims for at least this reason.

Second, the '667 patent fails to disclose a wound dressing that passively **lowers** the potential of a pathology. The Office Action concludes that antimicrobial metals inherently alter an electrodynamic process when they are in contact with a fluid. The Office Action further concludes that depending on the amount of metal present, an antimicrobial or analgesic effect occurs. The Office Action then concludes that this effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound. Applicant respectfully traverses these conclusions and submits that the conclusions in the Office Action are improperly applied because the Examiner has not provided any objective evidence to support these conclusions. Applicant respectfully requests the Examiner to provide at least one reference to support that antimicrobial metals inherently lower the electrical potential of a pathology. The only evidence in the record that discloses conductive fabrics that lower a pathology's potential is the Applicant's own disclosure.

Third, the Office Action alleges that antimicrobial metals inherently shift the electrical potential of a pathology because an electrochemical reaction takes place when a metal contacts a fluid. Applicant respectfully disagrees. Applicant draws the Examiner's attention to Figure 30 and pages 30-31 of the present specification. Figure 30 shows one embodiment of claimed subject matter in which a conductive wound dressing 110 forms an electrical bridge across a pathology and lowers the potential of the wound by contacting the uninjured skin surfaces on the sides of the wound. The point of maximum resistance shifts from point 39 to point 37.

Fourth, the pending claims are generally directed to wound dressings that **lower** the electrical potential of wound by an amount effective to promote healing. For example, claim 1

recites in part a wound dressing configured to passively lower the potential of a pathology in an amount effective to promote healing. The '667 patent fails to disclose a wound dressing that lowers the electrical potential of a pathology by an amount effective to promote healing. The Office Action concludes that the pathology's electrical potential would necessarily be lowered as an intrinsic consequence of the placement of the device disclosed by the '667 patent within the user's body because the cited reference allegedly uses the same conductive material. Applicant points out the surface resistivity is not the same between the claimed subject matter and the device of the '667 patent as described above. Moreover, nothing in the '667 patent discloses a conductive wound dressing that lowers electrical potential of a pathology by an amount effective to promote healing.

Fifth, the Office Action alleges that it is known that silver has an analgesic effect. Applicant respectfully disagrees, and requests that the Examiner provide objective evidence to support this conclusion. With regard to claim 31, Applicant points out that the analgesic effect is produced by interiorly shifting a pathology's maximum electrical resistance. The interior shift of electrical resistance cannot be achieved by the application of ionic silver as suggested in the Office Action. Instead, the shift is produced as described in Figure 30 of the present application.

With regard to claims 31 and 32, the Office Action concludes that it is an intrinsic consequence that the device interiorly shifts a pathology's maximum electrical resistance when in conductive contact with the pathology. Applicant respectfully disagrees. Claim 31 is directed to a medical device comprising at least one layer of conformable, conductive fabric material having a surface resistance less than about  $1 \text{ ohms/cm}^2$ , wherein said at least one layer of conformable, conductive fabric material comprises a biologically inert polymer and a conductor; and wherein said medical device induces an analgesic effect by interiorly shifting a pathology's maximum electrical resistance when applied to the pathology. Claim 32 has at least two plies wherein at least one layer of conductive material has a surface resistance less than about  $1 \text{ ohms/cm}^2$ . The '667 patent fails to disclose a device having a surface resistance less than about  $1 \text{ ohms/cm}^2$ . Moreover, the '667 patent fails to disclose a device that induces an analgesic effect by interiorly shifting a pathology's maximum electrical resistance. Accordingly, the '667 patent cannot anticipate claims 31 and 32.

Lastly, Applicant points out that none of the references cited in the Office Action

recognize the problems addressed by the claimed subject matter. The present application is the only disclosure describing a wound dressing that promotes healing and induces analgesic effects by lowering electrical potentials of wounds.

**6. Rejection of Claim 6 under 35 USC § 102(b)**

Claim 6 is rejected under 35 USC § 102(b) as allegedly being anticipated by U.S. Patent No. 4,615,705 ("the '705 patent") because the '705 patent allegedly discloses antimicrobial implants having at least one layer of conductive material. Applicant respectfully traverses this rejection.

As noted above, claim 1 is amended to be generally directed to a wound dressing comprising at least one layer of conformable, conductive fabric. The '705 patent fails to disclose a wound dressing having at least one layer of conformable, conductive fabric. As a result, the '705 patent cannot anticipate claim 6 because the '705 patent fails to disclose each element of the claim.

**7. Rejection of claims 3, 5, 7-12 under 35 U.S.C. § 103**

Claim 7 is rejected under 35 USC § 103(a) as allegedly being unpatentable over the '705 patent. Claims 3, 5 and 8-12 are rejected under 35 USC 103(a) as allegedly being unpatentable over the '667 patent. Applicant respectfully traverses these rejections.

**Relevant Law**

The United States Patent and Trademark Office (USPTO) has the burden of showing a prima facie case of obviousness. In re Bell, 991 F.2d 781, 783 (Fed. Cir. 1993). In determining obviousness, the invention must be considered as a whole, and the claims must be considered in their entirety. Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567 (Fed. Cir. 1983). A prima facie case of obviousness is established when the teachings from the prior art itself would have suggested the claimed subject matter to a person of ordinary skill in the art. In re Rhinehart, 531 F.2d 1048, 1051 (CCPA 1976). More specifically, the requirements for establishing a prima facie case of obviousness include: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

When a rejection depends on a combination of prior art references, the USPTO must show that there is some teaching, suggestion, or motivation to combine the references. In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987). The mere fact that the prior art could be modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). Finally, obviousness may not be established using hindsight. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1551 (Fed. Cir. 1983).

### **Analysis**

With regard to claim 7, the Office Action alleges that although the '705 patent fails to teach or suggest a dental appliance, the Office Action concludes that it would have been obvious by one of ordinary skill in the art to modify a dental implant by coating it with an antimicrobial metal. Claim 7 depends from claim 1 and incorporates the limitations of claim 1 including the limitation of at least one layer of a conformable, conductive fabric. The '705 patent fails to teach or suggest a dental appliance comprising at least one layer of a conformable, conductive fabric. Therefore, the '705 patent cannot render claim 7 obvious because it fails to teach or suggest every element of the claimed subject matter.

With regard to claims 3, 5 and 8-12, the Office Action concludes that it would have been obvious to one of ordinary skill in the art to modify the teachings of the '667 patent to arrive at the claimed subject matter. Applicant points out that the '667 patent fails to teach or suggest the wound dressing of claim 1, and because claims 3, 5, and 8-12 incorporate the limitations of claim 1, the '667 patent fails to teach or suggest all of the limitations of claims 3, 5, and 8-12.

Moreover, Applicant notes that the Declaration of Dr. Marx points out that the melt injected wound dressing disclosed by the '667 patent would have severely limited conductivity if molded or shaped as claimed. The high conductivity or low surface resistivity of the claimed conformable, conductive fabric wound dressings generate the analgesic or wound healing effects apart from the antimicrobial effects of silver. Thus, the wound dressing disclosed in the '667 patent cannot inherently induce an analgesic effect or promote wound healing because the surface conductivity of such a dressing would be significantly reduced if shaped as claimed.

**8. Allowable Subject Matter**

Applicant acknowledges with thanks that Claims 15-18 are allowable.

**9. New Claims**

New claims 34-36 are added to clarify and claim various additional aspects of the invention. Support for these amendments is found throughout the specification as originally filed; therefore, no new matter is introduced.



**CONCLUSION**

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1, 3, 4, 6-19, 23, 26-32, and 34-36 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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